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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,398	11/14/2003	James W. Lillard JR.		6848

7590 07/09/2008

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EXAMINER	
HALVORSON, MARK	
ART UNIT	PAPER NUMBER
1642	
MAIL DATE	DELIVERY MODE
07/09/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/712,398	LILLARD ET AL.	
	Examiner	Art Unit	
	Mark Halvorson	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *4/15/2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9-11 and 15-18* is/are pending in the application.

4a) Of the above claim(s) *16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-11,15,17 and 18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 9-11 and 15-18 are pending.

Election/Restrictions

Applicant's election of anti-CCL25 antibodies in the reply filed on April 15, 2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 16 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim.

Claims 9-11, 15, 17 and 18 are under examination.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 9-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Arenberg et al (J Clin Invest, 1996, 97:2792-2802).

The claims are drawn to a method of inhibiting malignant cell migration and metastasis in a host by administering of an effective amount of at least one antibody which is chosen to bind to a chemokine, wherein the host is a human.

Arenberg et al disclose the administration of an antibody to the chemokine IL-8 to reduce tumor growth of human non-small cell lung cancer in a mouse model of lung cancer. (page 2995, 2nd column).

Claims 9-11, 15 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 00/53635 (published September 14, 2000).

The claims are drawn to a method of inhibiting malignant cell migration and metastasis in a host by administering of an effective amount of at least one antibody which is chosen to bind to a chemokine, wherein the host is a human, wherein the antibody is humanized, wherein the antibodies are anti-CCL25 antibodies.

WO 00/53635 discloses the treatment of subjects with cancer with ant-TECK (anti-CCL25) antibodies wherein the antibody is human (page 21, lines 18 to page 23, line 26; page 46 lines 20-30), wherein the subject is human. (page 47 lines 20-21).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Arenberg et al in view of Queen et al (U.S. Patent 5530101, issued 6/96).

Claim 11 is drawn to a method of inhibiting malignant cell migration and metastasis in a host by administering of an effective amount of at least one antibody

which is chosen to bind to a chemokine, wherein the antibodies are human, humanized or chimeric.

Arenberg et al has been described supra.

Arenberg et al does not disclose the administration of anti-chemokine human, humanized or chimeric antibodies.

Queen et al r describes how to make a humanized antibody having CDRs from a donor antibody and heavy and light chain variable region frameworks from human acceptor antibody heavy and light chain frameworks (col 16, lines 27-42).

One of ordinary skill in the art would have been motivated to apply Queen et al's method of administration of humanized antibodies to Arenberg et al's method of administration of an antibody to the chemokine IL-8 because of the advantages of using humanzed antibodies for the treatment of chronic diseases. It would have been prima facie obvious to combine Arenberg et al's method of administration of an antibody to the chemokine IL-8 with Queen et al's method of administration of humanized antibodies Queen et al's method of administration of humanized antibodies prevent an immunogenic response against the mouse monoclonal antibody in order to treat patients with acute or chronic inflammatory reactions.

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Arenberg et al in view of DeLuka et al (US Patent No: 4,818,542, issued April 4, 1989).

Claim 18 is drawn to a method of inhibiting malignant cell migration and metastasis in a host by administering of an effective amount of at least one antibody which is chosen to bind to a chemokine, wherein the antibodies are administered in microspheres.

Arenberg et al has been described supra.

Arenberg et al does not disclose the administration of anti-chemokine antibodies in microspheres.

DeLuka et al disclose the administration of antibodies in microspheres (claim 1, column 6, lines 24-31)

One of ordinary skill in the art would have been motivated to apply DeLuka et al's method of administration of antibodies in microsphers to Arenberg et al's method of administration of an antibody to the chemokine IL-8 because of the advantages of using microspheres for the controlled release of drugs. It would have been prima facie obvious to combine Arenberg et al's method of administration of an antibody to the chemokine IL-8 with DeLuka et al's method of administration of antibodies in microsphers to adminster the anti-IL-8 antibody in a controlled release system.

Summary

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Halvorson, PhD whose telephone number is (571) 272-6539. The examiner can normally be reached on Monday through Friday from 8:30am to 5 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached at (571) 272-0832. The fax phone number for this Art Unit is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mark Halvorson
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/MISOOK YU/
Primary Examiner, Art Unit 1642